UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,078	10/21/2003	Jaymin C. Shah	PC23164A	4825

23913 7590 02/01/2007

PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
YEBASSA, DESTA LETTA	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,078	SHAH, JAYMIN C.	
	Examiner	Art Unit	
	Desta L. Yebassa	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 07/18/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made for the information disclosure statement filed on 07/18/2006. Receipt is also acknowledged for the oath and declaration filed on 05/19/2004.

Claims 1-18 are pending.

Claims 1-18 are rejected.

No claims are allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is the written description rejection.**

Independent claim 1 recites an "aryl-heterocyclic compound". However, There is no description or support or examples in the specification anywhere what is aryl-heterocyclic compound or what it includes. The specification only exemplifies ziprasidone, which has the structural formula (page 3, lines 1-10). However, this structure does not found.... in the claims. Claims 2-14 are rejected under this statute for depending from each other and in turn depending from claim 1 without clarifying this

issue, thereby incorporating the written description rejection. One of an ordinary skill in the art would have not readily recognize or concluded that applicants are in possession of the composition claimed. Therefore, the claimed composition fails to meet the requirement for an adequate written description of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for formulation comprises viscosity agents clamed in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and Whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a viscosity agents comprises a cellulose derivatives such as methyl cellulose, sodium carboxymethyl cellulose, hydroxypropyl methyl cellulose, polyethylene glycols polyethylene ethers, viscosified water, pharmaceutically acceptable oils and oil based agents and the like added to the depot formulation to provide necessary viscosity.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves to determine which viscosity agents exhibit the desired viscosity for the desired products. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting such broad term viscosity agents claimed in the invention. There are various types of viscosity agents known in

the prior art, which have different uses, function, properties, mechanisms and the like that may be incompatible with applicants depot formulation hetero-cyclic of compounds In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize claimed invention of such broad viscosity agents have the scope broader than the scope of the enablement.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present for the viscosity agents in the instant specifications found on page 5, lines 34-37 and page 6, lines 1-10) which provide a listing of viscosity agents such as methyl cellulose, sodium carboxymethyl cellulose, hydroxypropyl methyl cellulose, polyethylene glycols polyethylene ethers, viscosified water, pharmaceutically acceptable oils and oil based agents and the like. However, there is no such examples in the specification that demonstrates each type of viscosity agents and their use. The only example, set forth is example 1 (page 8, lines 20-37 through page 9. However, this is not sufficient to demonstrate this broad term viscosity agents. Furthermore, there is no depot formulation actually prepared in the instant specification which contains the listed type of viscosity agents.

The breadth of the claims

The breadth of the claims is the viscosity agents used in the preparation of injectable depot formulation claimed in claim 1.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what viscosity agents could be administered with applicants' instant claim 1 which would produce the necessary viscosity to have the formulation to assure the proper efficacy for treatment in psychotic disorder. There is little direction found in the specification as to what type of viscosity agents are considered to have the proper characterstics for the formulation except those given page 5, lines 34-37 and page 6, lines 1-10. While he level of skill in the art is high, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed to determine which viscosity agents exhibit the depot formulation desired pharmacological activity. Thus, the specification fails to provide sufficient support for the viscosity agents used. Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which type of viscosity agents could be used in the injectable depot formulation with hetero-cyclic compound, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsai et al. (U.S. Patent No. 6,228875).

Tsai et al disclose an injectable depot formulation of pharmaceutical composition comprising of typical antipsychotics include ziprasidone which is belong to aryl-heterocyclic group and a method for treating neuropsychiatric disorders include Schizophrenia, Alzheimer's Disease, depression and the like by administering effective amount of ziprasidone (abstract, column 1, lines 64-68, column 2, lines 58-67, column 3, lines 35, column 5, lines 65-67 and column 6, lines 1-5). Tsai et al also disclose pharmaceutical composition of viscosity agent include methyl cellulose, ethyl cellulose, sodium carboxymethyl cellulose, polyvinylpyrrolidone, hydroxypropylmethyl cellulose, gelatin, starch, micro-crystalline cellulose, and the like (column 7, lines 37-53). Tsai et al also disclose injectable compositions that may contain various carriers include polyols such as glycerol, polyethylene glycol, polypropylene, and the like (column 7, lines 361-65). Therefore, claims 1, 2, 6 and 8 are anticipated by Tsai et al.

2. Claims 1-5, 9-10, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (WO 97/41896).

Johnson et al discloses a formulation comprising of an aryl-heterocyclic compound such as ziprasdone and a cyclodextrin inclusion of complex, an aqueous solution and organic solvent and pharmaceutically acceptable salt of an aryl-heterocyclic compound (abstract and column 4, lines 10-20). The amount of recommended range for ziprasidone is 5-300 mgA/ml (page 9, lines 10-15) and a

cyclodextrin in a wide range of concentration from 5 % to 100 % w/v (column 9, lines 30 and column 7, lines1). Useful cyclodextrin include alpha, beta, and gamma cyclodextrins, methylated cyclodextrins, hydroxypropyl-beta-cyclodextrin (HPBCD), beta-cyclodextrin sulflbutylether (SBECD) (page 6, lines 30-32 and page 7, lines 8-10). Johnson et al also disclose ziprasidone salts include mesylate salt of ziprasidone, complexed with SBECD and HPBCD (page 7, lines 15-30). Crystalline inhibitors, polar Solvents used in the composition include tetrahydrofuran, water, lower alcohol (page 10, lines 10-18. Therefore, claims 1-5, 9-10, 12 and 15 are anticipated by Johnson et al.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lowe, III et al (U.S. Patent No. 4,831,031).

Lowe, III et al discloses formulation comprises of arylpiperazinyl-ethyl(or butyl)-heterocyclic compounds (column 1, lines25- 50). Specific preferred compounds listed see (column 2, lines 1-11). When Lowe teaches a viscosity agent ethanol (see example 1, line 49,) then the claim is fully anticipated. It is noted that there is no specific viscosity agent name. Therefore, claim 1 clearly anticipated by Lowe III et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3, 6-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsai et al. (U.S. Patent No. 6,228875) in view of Johnson et al. (WO 97/41896.

Tsai et al has been as applied above.

Tsai et al does not teach cyclodextrin. However, the secondary reference, Johnson et al teach this limitation.

Johnson et. teaches similar method and formulation of pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasdone and a cyclodextrin.

Johnson et al teaches a formulation comprising of pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasdone and a cyclodextrin (abstract and column 4, lines 10-20). The amount of ziprasidone is at least 2.5 mgA/ml at a cyclodextrin concentration of 40 % w/v in water, preferably, a recommended range for ziprasidone is 5-300 mgA/ml (page 5, lines 15-25 and page 9, lines 10-15) and a cyclodextrin in a wide range of concentration from 5 % to 100 % w/v (column 9, lines 30

and column 7, lines1). Useful cyclodextrin include alpha, beta, and gamma cyclodextrins, methylated cyclodextrins, hydroxypropyl-beta-cyclodextrin (HPBCD), beta-cyclodextrin sulflbutylether (SBECD) (page 6, lines 30-32 and page 7, lines 8-10). Johnson et al also disclose ziprasidone salts include mesylate salt of ziprasidone, complexed with SBECD and HPBCD (page 7, lines 15-30). Crystalline inhibitors, polar Solvents used in the formulation include tetrahydrofuran, water, lower alcohol (page 10, lines 10-18).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add the composition of Johnson et al to the composition of Tsai et al. since Johnson et al teaches similar composition for the same utility. The motivation to do so comes from secondary reference, Johnson et al who teaches complexing agent such as cyclodextrins and organic solvents that may used to increase the solubility, dissolution rate and stability of the formulation which leads to increase therapeutic efficacy of the drug. Therefore, one of ordinary skill in the art would have been motivated to make a pharmaceutical formulation comprising of an aryl-heterocyclic compound such as ziprasdone, viscosity agent and a cyclodextrin in similar condition by following the step of Tsai et al. and Johnson et al with reasonable expectation of success for treating a psychotic disorders.

2. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 97/41896) in view of Arenson et al (WO 0072847).

Johnson et al teaches a formulation comprising of pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasdone and a cyclodextrin (abstract and column 4, lines 10-20). The amount of ziprasidone is at least 2.5 mgA/ml at a cyclodextrin concentration of 40 % w/v in water, preferably, a recommended range for ziprasidone is 5-300 mgA/ml (page 5, lines 15-25 and page 9, lines 10-15) and a cyclodextrin in a wide range of concentration from 5 % to 100 % w/v (column 9, lines 30 and column 7, lines1). Useful cyclodextrin include alpha, beta, and gamma cyclodextrins, methylated cyclodextrins, hydroxypropyl-beta-cyclodextrin (HPBCD), beta-cyclodextrin sulflbutylether (SBECD) (page 6, lines 30-32 and page 7, lines 8-10). Johnson et al also disclose ziprasidone salts include mesylate salt of ziprasidone, complexed with SBECD and HPBCD (page 7, lines 15-30). Crystalline inhibitors, polar Solvents used in the formulation include tetrahydrofuran, water, lower alcohol (page 10, lines 10-18).

Johnson et al does not teach the viscosity agent, sodium carboxymethyl cellulose. However, the secondary reference, Arenson et al teach this limitation.

Arenson et al. teaches similar method and formulation of pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasdone and a viscosity agent.

Arenson et al teaches pharmaceutical formulation comprising of ziprasidone and pharmaceutically acceptable salts and viscosity agent (page 3, lines 15-16). The viscosity agent include cellulose derivatives such as sodium carboxymethylcellulose, and the like (page 6, lines 5-14).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add the composition of Arenson et al to the composition of Johnson et al since Arenson et al teach similar composition for the same utility. The motivation to do so comes from secondary reference, Arenson et al who teaches suspension ziprasidone and viscosity agent sodium carboxymethylcellulose which has advantageous than dissolved ziprasidone and more chemically stable and thereby improving chemical stability and as well as taste. Therefore, one of ordinary skill in the art would have been motivated to make a pharmaceutical formulation comprising of an aryl-heterocyclic compound such as ziprasdone, viscosity agent and a cyclodextrin in similar condition by following the step of Johnson et al and Arenson et al with reasonable expectation of success for treating a psychotic disorders.

3. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsai et al. (U.S. Patent No. 6,228875) in view of Johnson et al. (WO 97/41896) and Arenson et al (WO 0072847).

Tsai et al has been as applied above.

Tsai et al teaches dosage form and duration such as 1-1000 mg/day and 1-1000 mg/month and 30 mg/kg/day once a day by month for a period of 6 weeks (column 8, lines 65-67 and column 9, lines 1). Tsai et al. does not teach the duration form as instant claims. However, It would have been obvious to a person of ordinary skill in the art at the time invention was made to vary the duration of ziprasidone to optimize the effects desired. One of ordinary skill in the art at the time the invention was made would

have immediately envisioned that the specificity of the duration of the form was not critical to the composition and would have found obvious at the time the invention was made to vary the duration of the dosage form depending upon the seriousness of the patient or progresses of the condition of the patient.

Tsai et al does not teach the useful cyclodextrin include HPBCD and SBECD, its amount, sodium carboxymethyl cellulose and its amount as instant claims. However, the secondary references teach this limitation.

Johnson et al. teaches similar method and formulation of an aryl-heterocyclic compound HPBCD and SBECD.

Johnson et al teaches a composition comprising of pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasdone and a cyclodextrin (abstract and column 4, lines 10-20). The amount of ziprasidone is at least 2.5 mgA/ml at a cyclodextrin concentration of 40 % w/v in water, preferably, a recommended range for ziprasidone is 5-300 mgA/ml (page 5, lines 15-25 and page 9, lines 10-15) and a useful cyclodextrin include methylated cyclodextrins, hydroxypropyl-beta-cyclodextrin (HPBCD), beta-cyclodextrin sulflbutylether cyclodextrin in a wide range of concentration from 5 % to 100 % w/v (page 6, lines 30-32 and page 7, lines 8-10, page 9, lines 30 and page 7, lines1). Crystalline inhibitors, polar Solvents used in the formulation include tetrahydrofuran, water, lower alcohol (page 10, lines 10-18).

Arenson et al. teaches similar method and formulation of pharmaceutically acceptable salt of an aryl-heterocyclic compound such as ziprasdone and a viscosity agent.

Arenson et al disclose pharmaceutical composition comprising of ziprasidone and pharmaceutically acceptable salts and viscosity agent (page 3, lines 15-16). The viscosity agent include cellulose derivatives including sodium carboxymethylcellulose, and the like used in an amount of from about 0.01 % to about 10 % weight (page 6, lines 5-14).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add the composition of Johnson et al and Arenson et al to the composition of Tsai et al. since Johnson et al and Arenson et al teach similar composition for the same utility. The motivation to do so comes from secondary reference, Johnson et al who teaches complexing agent such as cyclodextrins and organic solvents that may used to increase the solubility, dissolution rate and stability of the formulation which leads to increase therapeutic efficacy of the drug and Arenson et al who teaches suspension ziprasidone and viscosity agent sodium carboxymethylcellulose which has advantageous than dissolved ziprasidone and more chemically stable and thereby improving chemical stability and as well as taste.. Therefore, one of ordinary skill in the art would have been motivated to make a pharmaceutical formulation comprising of an aryl-heterocyclic compound such as ziprasdone, viscosity agent and a cyclodextrin in similar condition by following the step of Tsai et al., Johnson et al and Arenson et al with reasonable expectation of success for treating a psychotic disorders.

4. Claims 1, 2, 3, 13 and 14 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Johnson et al. (WO 97/41896) in view of chemical abstracts 138:309 126 (CHEM abs 126) and Faour et al (US 2002/0132005).

Johnson et al. has been as applied above.

Johnson et. teaches method and formulation of an aryl-heterocyclic compound such as ziprasdone and a cyclodextrin.

Johnson et al. does not teach viscosity and number of cps. However, the secondary references, teach this limitation.

Chemical Abs 126 teaches formulation of controlled release drugs comprising an aryl-heterocyclic compound and an addition of sodium carboxycellulose polymer (NaCMC) that allows this aryl-heterocyclic drug to be dosed in a time release form without the possible large-dose risk factors. The preparation of the formulation shows different combination of Na CMC and the aryl-heterocyclic drug that gave different time release data. The abstract does not encompass various concentrations which translate to various viscosities (i.e. cps) and do not specifically give the viscosity numbers. However, Faour et al teaches in a similar process using an aryl-heterocyclic and viscosity agent include hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethylcellulose having viscosity from 3 to 100,000 cps (page 5, paragraph 0050). Faour et al also teaches formulation comprising anti-psychotic agent (page 2 through page 3, paragraph 0030) and typical example of antipsychotics include ziprasidone (page 10, paragraph 0106). Therefore, one of ordinary skill in the art looking to avoid a large-dose risk factors in dispensing aryl-heterocyclic drugs would motivated to use a water soluble polymer such as Na CMC in a drug formulation as taught by

Chem abs 126 with an expectation of having a viscosity agent (NaCMC) which would give slow release of the active aryl-heterocyclic to sustain a level drug dosage and to avoid over dosing with a large dose.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, Ph.D.
Patent Examiner
Art Unit 1615

JEAN F. VOLLANO
SPECIAL PROGRAM EXAMINER

Jean F Vollano